I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: **Commissioner for Patents** 

P. O. Box 1450

Alexandria, VA 22313-1450

on September 6, 2005

TOWNSEND and TOWNSEND and CREW LLP



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Harald STEIN and Horst DURKOP

Application No.: 10/612,832

Filed: July 1, 2003

For: AGENT FOR USE IN DIAGNOSTICS AND THERAPY Confirmation No. 3864

Examiner: Yao, Lei

Technology Center/Art Unit: 1642

DECLARATION REGARDING DEPOSIT

Docket No.: 086035-000000US

Client Ref. No.: PA34271US-031/wl

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The undersigned, PROF, DR. M. STRIN authorized to act on behalf of the Applicant and Assignee in matters relating to the subject Patent Application, does hereby declare and state that:

1. The cell line designated DSZ1 described at, e.g., p. 9, third paragraph of the above-captioned application, was deposited at the German Microorganisms Collection (DSM) under accession number DSM ACC2548. The deposit was made pursuant to the provisions of the Budapest Treaty. A copy of the deposit certificate is attached as Exhibit 1.

Page 2

- 2. The cell lines identified in paragraphs 1 above will be maintained at the DSM and replaced in the event of mutation, nonviability or destruction for a period of at least five years after the most recent request for release of a sample was received by DSM for a period of at least thirty years after the date of the deposit, or during the enforceable life of the related patent, whichever period is longest.
- 3. All restrictions, on the availability to the public of the cell line identified in paragraphs 1 above will be irrevocably removed upon the issuance of a patent from the above-captioned application.
- 4. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 8/17/2005

By:

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60520126 v1

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**PATENT** 

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Date: 8/17/2000

By: Sont Del

POSITION OF PATHOLOGIC

60520126 v1

#### BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE



## INTERNATIONAL FORM

Universitätsklinikum Benjamin Franklin Institute of Pathology FU Berlin Hindenburgdamm 30

12200 Berlin

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT Issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page

I IDENTIFICATION OF THE MICROORGANISM			
	on reference given by the DEPOSITOR: SZ1	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:  DSM ACC2548	
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION			
The microorganism identified under I. above was accompanied by:			
(Mark with	(X) a scientific description () a proposed taxonomic designation a cross where applicable).		
(II. RECEIPT AND ACCEPTANCE			
This International Depositary Authority accepts the microorganism identified under I. above, which was received by it on 2002-06-05 (Date of the original deposity).			
IV. RECEIPT OF REQUEST FOR CONVERSION			
The microorganism identified under I above was received by this International Depositary Authority on and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion).			
V. INTERNATIONAL DEPOSITARY AUTHORITY			
Name:	DSMZ-DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH Mascheroder Weg 1b D-38124 Bruunschweig	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(a):  Date: 2002-06-12	

Where Rule 6.4 (d) applies, such date is the date on which the status of international depositary authority was acquired. Form DSMZ-BF/4 (sole page) 12/2001

# BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE



### INTERNATIONAL FORM

Universitätsklinikum Benjamin Franklin Institute of Pathology FU Berlin

Hindenburgdamm 30 12200 Berlin

VIABILITY STATEMENT issued pursuant to Rulo 10.2 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page

I. DEPOSITOR		IL IDENTIFICATION OF THE MICROORGANISM
Name: Address:	Universitätsklinikum Benjamin Franktin Institute of Pathology FU Berlin Hindenburgdamin 30 12200 Berlin	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:  DSM ACC2548  Date of the deposit or the transfer!:  2002-06-05
III. VIABIL	TTY STATEMENT	
On that date	y of the microorganism identified under II above was tested on the suid microorganism was  y viable  y no longer viable	2002-06-05 3.
` '	TIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PER	FORMED <sup>4</sup>
v. intern	ATIONAL DEPOSITARY AUTHORITY	
Name: Address:	DSMZ-DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH Mascheroder Weg 1b D-38124 Braunschweig	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):  Date: 2002-06-12

Indicate the date of original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).

In the cases referred to in Rule 10.2(a) (ii) and (iii), refer to the most recent viability test.

Mark with a cross the applicable box.

Fill in if the information has been requested and if the results of the test were negative.

Form DSMZ-BP/9 (sole page) 12/2001